K090656 #4

Summary of Safety and Effectiveness
Smith & Nephew, Inc. InterTAN® CHS Limited Collapse Set Screw

Contact Person and Address
Shereen Myers
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Orthopaedic Division
1450 East Brooks Road
Memphis, Tennessee 38116
T (901) 399-6325

Date of Summary: March 5, 2009

JUN - 3 2009

Name of Device: Smith & Nephew, Inc. InterTAN® CHS Limited Collapse Set Screw
Common Name: Screw
Device Classification Name and Reference: 21 CFR 888.3040, smooth or threaded metallic bone fixation fastener
Device Class: Class II
Panel Code: Orthopaedics/87 HWC

Device Description

Subject of this Traditional 510(k) premarket notification is the InterTAN® CHS Limited Collapse Set Screw. The subject device is a line addition to the InterTAN® CHS Plate System cleared via K080434. The Limited Collapse Set Screw is designed to limit the amount of allowable collapse and prevent lateral advancement of the plate.

Mechanical Testing

A review of the mechanical data indicates that the Limited Collapse Set Screw is capable of withstanding expected *in vivo* loading without failure.

Intended Use

InterTAN CHS Limited Collapse Set Screw is indicated for:

- Intracapsular fractures of the proximal femur (For certain high subcapsular fractures, it may be more prudent to select a prosthesis in lieu of internal fixation to reduce the risk of nonunion or AVN of the femoral head).
- Intertrochanteric fractures.
- Stable and unstable fractures of the proximal femur in which medial cortex stability can be restored.
- Hip osteotomy

InterTAN CHS Limited Collapse Set Screw is for single use only and is to be used with InterTAN® CHS Plating System.

Substantial Equivalence Information

The substantial equivalence of the InterTAN® CHS Limited Collapse Set Screw is based on its similarities in indications for use, design features, operational principles, and material composition to the Smith & Nephew, Inc. InterTAN® CHS Plate System (K080434) and the DePuy PEAK FX Hip Plate [Limited collapse cap] (K063509).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Smith & Nephew , Incorporated
% Ms. Shereen Myers
Regulatory Affairs Specialist I
1450 East Brooks Road
Memphis, Tennessee 38116

JUN - 3 2009

Re: K090656
Trade/Device Name: InterTAN CHS Limited Collapse Set Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: March 5, 2009
Received: March 12, 2009

Dear Ms. Myers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting

(reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/cdrh/comp/ for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buehrer for

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090656

Device Name: Smith & Nephew, Inc. InterTAN® CHS Limited Collapse Set Screw

Indications for Use:

InterTAN CHS Limited Collapse Set Screw is indicated for:

- Intracapsular fractures of the proximal femur (For certain high subcapsular fractures, it may be more prudent to select a prosthesis in lieu of internal fixation to reduce the risk of nonunion or AVN of the femoral head).
- Intertrochanteric fractures.
- Stable and unstable fractures of the proximal femur in which medial cortex stability can be restored.
- Hip osteotomy

The Limited Collapse Set Screw is for single use only and is intended to be used with InterTAN® CHS Locked Plating System.

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090656